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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/331,376	06/18/1999	OYSTEIN FODSTAD	7885.65USWO	1579

23552 7590 07/15/2003

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MINNEAPOLIS, MN 55402-0903

EXAMINER
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DAVIS, MINH TAM B

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 07/15/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

09/331,376

Applicant(s)

FODSTAD ET AL.

Examiner

MINH-TAM DAVIS

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4, 6-11 and 13-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-11, 13-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Accordingly, claims 1-4, 6-11, 13-17 are examined in the instant application.

### **REJECTION UNDER 35 USC 103**

Claims 1-4, 6-11, 13-17 remain rejected under 35 USC 103 as being obvious over Hajek et al, in view of Fodstad et al, and O'briant et al, for reasons already of record in paper No: 25.

Applicant argues that Hajek et al do not teach or suggest a way to identify, screen or determine morphology of cells in suspension, and that Hajek et al teach identifying cells only when the cells are smeared on slides and stained.

Applicant argues that Fodstad et al teach a single type of antibody-particle complex for detecting a single type of target cells, and that the method performed by Fodstad et al would have a low possibility of aggregation when compared with using several types of particles. Applicant argues that Fodstad et al teach cell suspension is rapid and simple when a single type of target cell is analyzed using a single type of antibody-particle complex.

Applicant argues that there is no teaching or suggestion in either reference for performing the present method.

Applicant's arguments in paper No:26 have been considered but are found not to be persuasive for the following reasons:

It is noted that the claimed method is not limited to using a high concentration of cells, i.e. cells with counts of 40-50,000 cells or greater per microliter.

The claimed method is the same as the method taught Hajek et al, with only one difference, i.e. instead of smearing a sample on slides for detecting and phenotyping target cells under a microscope, the cells are in suspension while detected under a microscope.

It would have been obvious to replace the smearing method taught by Hajek et al with detection of the target cells in suspension under a microscope, because detection of the target cells in suspension under a microscope, as taught by Fodstad et al, is commonly used in the art, and would provide the same results as detection by smearing the sample on a slide, for normal cell concentration, i.e. in the range of 4-11,000 cells per microliter. One of ordinary skill in the art would have a reasonable expectation of success using a method to detect and phenotype target cells wherein the cells are detected while in suspension, because for normal cell concentration, i.e. in the range of 4-11000 cells per microliter, the cell clumping would not occur, when using different particles with different associated antigens, as taught by Hajek et al (Hajek et al, column 12, lines 37-49).

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

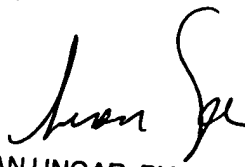
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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 703-305-2008. The examiner can normally be reached on 9:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANTHONY CAPUTA can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.

  
SUSAN UNGAR, PH.D  
PRIMARY EXAMINER

MINH TAM DAVIS

July 2, 2003